

Food and Drug Administration Rockville MD 20857

April 4, 2001

Dear Speakers, Members and Guests:

Thank you for your willingness to participate in the Pediatric Advisory Subcommittee meeting on Monday, April 23, 2001.

The focus of the meeting is chronic hepatitis C virus (HCV) infection in pediatric patients. Drugs and biologicals are approved for the treatment of chronic HCV in adults. When is it appropriate to evaluate these therapies in children and in what subset of chronically HCV-infected children? These and other issues in the development of therapeutic products for children with chronic HCV infection will be discussed.

The speakers will provide you with information on the hepatitis C virus, chronic HCV infection in adults, the natural history and available therapies, and what is known about HCV infection in children. The articles included in this package may be helpful in your preparation.

Looking forward to seeing you on April 23, 2001.

Sincerely,

Rosemary Roberts, M.D.

Team Leader, Pediatric Team

CDER, FDA

Attachments